



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

October 6, 2000

**VIA FEDERAL EXPRESS**

Dr. Pennell C. Painter  
Director of Clinical Chemistry  
University of Tennessee Medical Center  
1924 Alcoa Highway  
Knoxville, TN 37920

**Warning Letter No. 01-NSV-01**

**Dear Dr. Painter:**

During an inspection of Dynacare Tennessee, LLC, located at 1924 Alcoa Highway, Knoxville, Tennessee, on May 4-5, 2000, our investigator documented violations of Section 361 of the Public Health Service Act (PHS Act) and Title 21, Code of Federal Regulations, Part 1270, as follows:

- Failure to follow your written procedures and failure to properly interpret viral testing results for eye bank sample 004-00-282, which tested repeatedly reactive for hepatitis C upon initial testing in duplicate. The sample was subsequently retested twice, in duplicate, and inappropriately reported to the eye bank as non-reactive for hepatitis C.
- Failure to have written standard operating procedures (SOPs) that adequately address the handling and testing of eye bank samples. A review of 53 eye bank sample records revealed that 22 samples had been initially tested in duplicate, and 31 samples were initially tested only once. Further, your SOPs fail to detail a method for disqualifying samples because of sample integrity issues such as extreme hemolysis, or the procedure for interpreting results of eye bank samples.
- Failure to adequately supervise interpretation of test results in accordance with your SOP as evidenced by the fact that a second person did not review the testing results of eye bank sample 004-00-282.

The above noted deviations are not intended to be an inclusive list of all possible deficiencies at your facility. It is your responsibility to assure compliance with the applicable laws and regulations.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action, such as injunction, without further notice.

Please notify this office in writing, within 30 days of receipt of this letter, of the specific steps you have taken to address the noted deviations and to prevent any recurrence.

Your reply should be directed to the attention of Frank J. Jancarek, Compliance Officer, at the following address:

Food and Drug Administration  
297 Plus Park Boulevard  
Nashville, Tennessee 37217

Sincerely,

A handwritten signature in black ink, appearing to read "Carl E. Draper", with a stylized flourish at the end.

Carl E. Draper  
Director, New Orleans District

CED:FJJ:man